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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,480	08/13/2002	Robert Heger	49619	4809

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,480

Applicant(s)

HEGER ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-21 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response dated 12/05/05.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 15-21 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of List et al (USPN 5,389,382 hereafter '382), Buseti et al (USPN 6,190,692 hereafter '692) and Liversidge et al (USPN 6,045,829 hereafter '829). The claims are drawn to process for making a nanoparticle with a core and coating/shell. The core comprises the drug and a polymer while the coating is a water swellable polymer. The nanoparticles are > 1 micron in size.

4. The '382 patent discloses a hydrosol of a pharmaceutical agent in an intravenous applicable, stabilized form, which is suspended or is dry and re-suspendable in an aqueous medium. The hydrosol contains solid active agent particles (abstract). The hydrosol is started

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from a solution of a hardly water-soluble active substance in a water-miscible solvent. This solution is mixed with a relatively large amount of water containing a water-soluble colloid, for example gelatin. Alternatively or additionally, a water-insoluble colloid can be dissolved in the organic solvent. The colloid stabilized that active substance hydrosol formed when the phases are brought together. The organic solvent is then removed. In Examples 4,9 and 10 the active agent and ethyl cellulose are first dissolved in ethanol. The ethanolic phase is then stirred into an aqueous phase containing gelatin or a collagen hydrolysate. The ethanol is evaporated. The average diameter of the suspended particles is 245 nm, 129 nm, and 320 nm. The nanoparticles and their hydrosols correspond to the preparations defined in the instant claims. Ethyl cellulose acts as the core polymer, while gelatin or collagen hydrolysate act as the sheathing/coating polymers. The reference discloses a batch and spray methods of production, which are interchangeable in the art. Batch and continuous nanoparticle methods are well known in the art and are used interchangeably as can be seen in the '629 patent.

5. The '692 patent discloses a continuous spraying process for making nanoparticles (examples) where the active agent is together with a binder such as acrylic polymers and methacrylic acid (col. 8, lin. 30-45) and further coated with a water swellable polymer in an aqueous solution such as gelatin (col. 10, lin. 26-30). The cores can be further coated with a swellable coating polymer to increase the size of the particles (col. 10, lin. 55-67). The spraying process uses organic solvents to apply the coating layer (col. 11, lin. 12-28). The coatings are also applied using fluidized bed and pan coating methods (examples).

6. The '382 patent however is silent to the inclusion of casein or sodium casienate in the polymer coating shell, though the inclusion of the polymer is well within the level of skill in the

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art. The '892 patent discloses surface stabilized nanoparticles (abstract). The surface stabilizers are used in conjunction other stabilizers and include water soluble and insoluble polymers (col. 7, lin. 18-25). Some of the stabilizers include gelatin, casein and lecithin (col. 7, lin.; 30-35). The particles are made continuously by mixing the drug with a cellulosic polymers and further spray drying the resultant (col. 10, lin. 9-28). The resultant particles range in size from 100 to 400 nm (claims). An artisan of ordinary skill would have been motivated to include the excipients, including the casein of the '892 patent in to the formulation in order to modify the release rate of the coated drug, and improve its' stability.

7. With these things in mind it would have been motivated to follow the suggestions of the '382 patent to include similar compound to that of gelatin in the form of the casein disclosed by the '892 patent. An artisan would have also been motivated to produce the nanoparticles in either a batch or continuous method as taught by the '692 patent. The choice of method would be within the discretion of the skilled artisan since each method is seen as equivalent in the art. Barring a showing of unexpected results, it would have been obvious to combine these teachings in order to provide improved rate releasing properties and stability. It would have been obvious to combine the teachings with an expected result of a coated drug with improved stability and rate release properties.

Response to Arguments

8. Applicant's arguments with respect to claims 15-25 have been considered but are moot in view of the new ground(s) of rejection.

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Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618


MP Young


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER